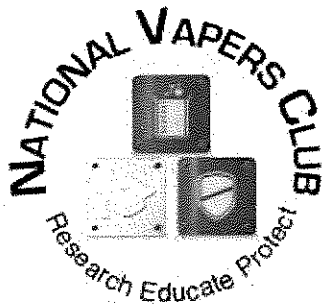

National Vapers Club

Addendum to OMB/OIRA Meeting

Specific Violations of Executive Order 12866

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V. Specific Violations of Executive Order 12866

The draft deeming regulations violate Executive Order 12866 in five specific ways:

1. **The regulations violate Executive Order 12866, Section 1(b)(6): "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."**

   Based on my analysis, the benefits of the proposed regulations do not justify the costs. The public health benefits of the regulations are indirect and minimal. More importantly, there are delayed in time. It will take many years before the FDA can review the tens of thousands of applications that could potentially be submitted. In the meantime, urgent public health issues regarding e-cigarettes, such as exploding batteries, will continue to cause public harm.

   Moreover, FDA review of complex PMTAs does little to directly address safety issues. The regulations do not actually specify any safety standards that need to be followed.

   Furthermore, the review of PMTAs for electronic cigarettes, which are as a category far less harmful than tobacco cigarettes, serves essentially no public health purpose. In fact, the costs outweigh the benefits because the result of the regulation will be to decimate the e-cigarette industry, causing many thousands of ex-smokers to return to smoking and deterring many thousands of smokers who might have quit in the future not to do so.

   Finally, the FDA has violated section 6 of the Executive Order by failing to identify the costs of the proposed regulation in terms of the following:
   a. Effects on the potential future growth of safer nicotine delivery products to the market;
   b. The decreased availability of electronic cigarettes and vaping products to consumers;
   c. The stifling of innovation in the electronic cigarette and vaping market;
   d. The effects on ex-smokers who have quit using e-cigarettes of having their electronic cigarette brand potentially removed from the market;
   e. The effects on current smokers of removing huge numbers and types of electronic cigarettes from the market, and thus potentially dissuading them from making quit attempts using these products.

2. **The regulations violate Executive Order 12866, Section 1(b)(8): "Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt."**

   The FDA failed to identify and assess an alternative form of regulation, specifically, one which would specify performance objectives rather than requiring a complex and burdensome manner of compliance that the regulated entities must adopt. As an alternative, the FDA could have simply promulgated uniform safety standards for all electronic cigarette and vaping products. These standards could have included issues such as battery safety and overcharge protection, quality assurance and control, leak-proof containers, childproof packaging, adequate regulation of temperature to avoid the production of formaldehyde and other degradation products of

propylene glycol and glycerin, prohibition of flavorings known to cause human disease (e.g., diacetyl), and use of safe manufacturing practices.

3. **The regulations violate Executive Order 12866, Section 1(b)(5): "When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective."**

   The proposed regulations are far from the most cost-effective manner to achieve the regulatory objective. Far more cost-effective would have been to propose regulations which would have specified performance objectives rather than requiring a complex and burdensome manner of compliance that the regulated entities must adopt. As an alternative, the FDA could have simply promulgated uniform safety standards for all electronic cigarette and vaping products. These standards could have included issues such as battery safety and overcharge protection, quality assurance and control, leak-proof containers, childproof packaging, adequate regulation of temperature to avoid the production of formaldehyde and other degradation products of propylene glycol and glycerin, prohibition of flavorings known to cause human disease (e.g., diacetyl), and use of safe manufacturing practices.

4. **The regulations violate Executive Order 12866, section 1(b)(11): "Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations."**

   The proposed regulations impose the most burdensome possible requirements on businesses, particular those of moderate and small size, while a much less burdensome alternative (direct regulation of vaping products via the establishment of uniform, minimum safety standards) is readily available and which would achieve the regulatory objectives not only more efficiently, but more effectively as well.

5. **The regulations violate Executive Order 12866, Section 1(b)(12): "Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty."**

   The proposed regulations are about as complex as could be imagined. The process proscribed for preparing PMTAs is complex, tedious, burdensome, and scientifically complicated. It would take a group of expert scientists in multiple areas, including epidemiology, toxicology, chemistry, population modeling, statistical modeling, human behavior, communication and perception, marketing behavior, and biostatistics to understand the multitude and nature of specific studies that would be required to derive the information necessary to make the required demonstrations specified for the PMTA. The overwhelming majority of businesses that would be regulated do not have the necessary expertise to understand the regulation, much less to comply with it.

   In contrast, if the agency simply set uniform safety standards, these could easily be understood by all regulated businesses.

National Vapers Club

Addendum to

OMB/OIRA Meeting

E-Cigarettes Poised to Save Medicaid Billions

State Budget Solutions Policy Analysis

By J. Scott Moody, Chief Executive Officer and

Chief Economist

National Vapers Club Board of Directors

STATE BUDGET SOLUTIONS

POLICY ANALYSIS

MARCH 31, 2015

E-Cigarettes Poised to Save Medicaid Billions

J. Scott Moody, Chief Executive Officer and Chief Economist

Electronic cigarettes (e-cigs) have only been around since 2006, yet their potential to dramatically reduce the damaging health impacts of traditional cigarettes has garnered significant attention and credibility. Numerous scientific studies show that e-cigs not only reduce the harm from smoking, but can also be a part of the successful path to smoking cessation.

The term "e-cig" is misleading because there is no tobacco in an e-cig, unlike a traditional, combustible cigarette. The e-cig uses a battery-powered vaporizer to deliver nicotine via a propylene-glycol solution—which is why "smoking" an e-cig is called "vaping." The vapor is inhaled like a smoke from a cigarette, but does not contain the carcinogens found in tobacco smoke.

Unlike traditional nicotine replacement therapy (NRT), such as gum or patches, e-cigs mimic the physical routine of smoking a cigarette. As such, e-cigs fulfill both the chemical need for nicotine and physical stimuli of smoking. This powerful combination has led to the increasing demand for e-cigs—8.2% use among nondaily smokers and 6.2% use among daily smokers in 2011.[1]

The game-changing potential for dramatic harm reduction by current smokers using e-cigs will flow directly into lower healthcare costs dealing with the morbidity and mortality stemming from smoking combustible cigarettes. These benefits will particularly impact the Medicaid system where the prevalence of cigarette smoking is twice that of the general public (51% versus 21%, respectively).

Based on the findings of a rigorous and comprehensive study on the impact of cigarette smoking on Medicaid spending, the potential savings of e-cig adoption, and the resulting tobacco smoking cessation and harm reduction, could have been up to $48 billion in Fiscal Year (FY) 2012.[2] This savings is 87% higher than all state cigarette tax collections and tobacco settlement collections ($24.4 billion) collected in that same year.

Unfortunately, the tantalizing benefits stemming from e-cigs may not come to fruition if artificial barriers slow their adoption among current smokers. These threats range from the Food and Drug Administration regulating e-cigs as a pharmaceutical to states extending their cigarette tax to e-cigs. To be sure, e-cigs are still a new product and should be closely monitored for long-term health effects. However, given the long-term fiscal challenges facing Medicaid, the prospect of large e-cigs cost savings is worth a non-interventionist approach until hard evidence proves otherwise.